

## REMARKS/ARGUMENTS

The rejections presented in the final Office Action dated October 19, 2005 (hereinafter final Office Action) have been considered. Claims 1-10 and 18-20 remain pending in the application. Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1-8 and 18-20 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,757,827 to *Buchbinder et al.* (hereinafter "*Buchbinder*"). Applicant maintains that claims 1-8 and 18-20 are not anticipated by *Buchbinder*. In view of the Examiner's comments to Applicant's prior response in the final Office Action, Applicant provides the following arguments directed to the Examiner's comments and the bases for rejecting the pending claims.

Applicant's response should be considered in view of clear factual errors in the characterization of the asserted reference and the bases for rejecting the claims. In particular, the Examiner's comments on Applicant's prior response in the final Office Action evidence such errors and mischaracterizations of *Buchbinder*. Applicant respectfully requests consideration of the following remarks and reconsideration of the rejection of claims 1-8 and 18-20.

*Buchbinder* discloses a steerable guidewire that includes tubing (2, 21, 41, 63) and a deflection wire (3, 23, 42, 64) arranged axially therein. The distal end of the tubing is shaped for reception within a spring coil (7, 22, 45). The deflection wire is tapered and ground to a sharp point (14). The distal point of the deflection wire terminates at a cap or tip (9, 31, 48).

*Buchbinder* fails to teach, expressly or inherently, a flexible shaft having a distal end shaped for accessing a target vessel. The distal end of the tubing (2, 21, 41, 63) in *Buchbinder* is shaped for reception within a spring coil (7, 22, 45), not for accessing a target

vessel. The sharp point of the deflection wire terminates at a cap of the spring coil, and is clearly unsuitable for accessing a target vessel, as the sharp point may undesirably puncture such a vessel. The spring coil is not described as being shaped, and clearly is not described as being shaped for accessing a target vessel.

For at least these reasons, *Buchbinder* fails to anticipate Applicant's claims 1-8 and 18-20, and the final rejection of Applicant's claims can not be sustained.

Applicant's claim 1 recites a handle assembly movably coupled to the flexible shaft, which provides relative movement therebetween in a manner further described in claim 1. In contrast, the proximal end of tubing (e.g., 63) in *Buchbinder* terminates within the distal portion of the tip rotation knob 61, and rotates in concert with knob 61 when knob 61 is rotated (*see, e.g.*, column 4, lines 36-38 and 50-52). No relative motion between knob 61 and tube 63 is possible.

For at least this reason, *Buchbinder* fails to anticipate Applicant's claims 1-8, and the final rejection of these claims can not be sustained.

The *Buchbinder* apparatus employs threads 66, 67 of deflection member 65 to provide continuous axial displacement of a deflection wire 64. When tip deflection knob 62 is rotated, deflection member 65 is caused to move in an axial direction, that is, either proximally or distally, and deflection wire 64 move similarly in axial motion relative to tubing 63. *Buchbinder* further teaches that axial motion of tip deflection knob 62 is restrained by annular projection 68.

*Buchbinder* clearly fails to teach a flexible shaft that is selectably movable between a plurality of discrete positions of a first degree-of-freedom defined relative to the flexible shaft. The *Buchbinder* apparatus cannot provide such movement because axial motion of its tip deflection knob 62 is restrained by annular projection 68, which represents a single non-selectable position, and the threads 66, 67 of deflection member 65 provide only continuous axial displacement of a deflection wire 64.

The Examiner appears to acknowledge the continuous axial displacement feature of *Buchbinder* in the final Office Action by stating that "[f]or the record, the device of

Buchbinder is fully capable of an infinite amount of degree of freedom.” Page 4 of the final Office Action, *emphasis added*.

Applicant, as described in paragraph 26 of Applicant’s specification, teaches that “[i]t will be appreciated that the physician can longitudinally and rotationally move the shaft 102 without the use of the handle 124. The handle 124, however, provides a restraint on this motion, thereby allowing such movements to be systematic and controllable.” *Emphasis added*.

The manner in which this “restraint” on shaft motion is implemented is clearly recited in Applicant’s claims 1 and 18. Claim 1 recites a flexible shaft that is selectably movable between a plurality of discrete positions of a first degree-of-freedom defined relative to the flexible shaft. Claim 18 recites means for restraining a motion of the shaft in the first degree-of-freedom at each position of the plurality of discrete positions.

The term “discrete” is understood to mean individually separate and distinct, as is defined, for example, in The New Oxford American Dictionary, Oxford University Press, Inc. (2001), p. 488. Applicant’s recitation of “discrete” positions in the claims is clearly not met by an apparatus that allows for “an infinite amount of degree of freedom.” The Examiner’s characterization of the *Buchbinder* apparatus is factually in error and effectively ignores an important feature of Applicant’s claims.

For at least this reason, *Buchbinder* fails to anticipate Applicant’s claims 1-8 and 18-20, and the final rejection of Applicant’s claims can not be sustained.

*Buchbinder* fails to teach the features of claims 2 and 3, since *Buchbinder* fails to teach a flexible shaft that is selectably movable between a plurality of discrete positions of a first degree-of-freedom defined relative to the flexible shaft. Applicant’s claims 2 and 3 recite alternative implementations involving the plurality of discrete positions of a first degree-of-freedom, neither of which is taught in *Buchbinder*.

*Buchbinder* fails to teach a tightening member as recited in claims 4-6, which provides a releasable coupling between the flexible shaft and the handle assembly. As

discussed above, *Buchbinder* provides for no relative motion between its tubing and deflection knob.

*Buchbinder* does not teach nor describe a hemostatic valve seal that is rotatable, as is recited in Applicant's claim 6.

*Buchbinder* fails to teach a handle assembly that includes a housing and a guide member attached to a flexible shaft, where the guide member is restrained in a first-degree-of-freedom relative to the housing at each position of a plurality of positions and movable relative to the housing through the displacement of the second degree-of-freedom at each position of the plurality of positions. *Buchbinder* clearly does not teach such a guide member, nor does *Buchbinder* describe an arrangement that provides for relative motion between its tubing and deflection knob.

Concerning claim 8, *Buchbinder* fails to teach a housing handle assembly that includes a guide member attached to a flexible shaft, and a housing movably coupled to the guide member via a slot and pin arrangement. The *Buchbinder* apparatus employs threads 66, 67 of deflection member 65 to provide continuous axial displacement of a deflection wire 64. *Buchbinder* wholly fails to teach a slot and pin arrangement as contemplated in Applicant's claim 8. Moreover, the *Buchbinder* arrangement fails to provide for relative motion between its tubing and deflection knob.

Applicant's dependent claims 19 and 20 are similarly not anticipated by *Buchbinder* for reasons discussed above.

To anticipate a claim, the asserted reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. All claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

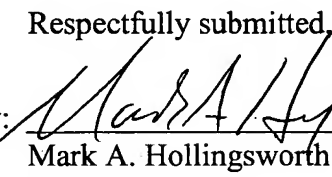
Applicant has provided hereinabove persuasive arguments that demonstrate that *Buchbinder* fails to teach every element of Applicant's claims 1-8 and 18-20. Applicant has further demonstrated that the final Office Action contains material factual errors concerning

the characterization of *Buchbinder* and the application of the *Buchbinder* teachings to Applicant's claimed subject matter. These factual errors form the basis supporting the Examiner's final rejection of the pending claims.

Applicant respectfully asserts that the bases for rejecting Applicant's pending claims in the first Office Action and the final Office Action are improper and can not be sustained. Applicant respectfully requests removal of finality of the instant Office Action and reconsideration of the application in view of these remarks.

It is believed that the pending claims are in condition for allowance, and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if prosecution of this application may be assisted thereby. Authorization is given to charge Deposit Account No. 50-3581 (GUID.027US01) any necessary fees for this filing.

Date: 12-19-2005

Respectfully submitted,  
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